

and malignant calcification clusters and the statistical likelihood of malignancy using the predefined classifier seen in Figures 4 and 5A-5J.”¹ The Office asserts that Bamberger “discloses in great detail the detecting and segmenting of mammographic images in determining a wide range of information regarding breast calcifications.”²

There are three basic criteria to establish a *prima facie* case of obviousness. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings, a reasonable expectation of success, and the prior art reference (or references when combined) must teach or suggest all the claim limitations.³ Where a *prima facie* case of obviousness is not supported by the facts, as is the case here, the applicant is under no obligation to submit evidence of nonobviousness.⁴

Claim 1

A method of differentiating benign from malignant calcifications comprising the steps of: detecting and segmenting breast calcifications from mammographic images of a patient; analyzing the shape and distribution of the calcifications and estimation of preselected parameters using image and non-image data from the patient's file and demography; and differentiating between benign and malignant calcification clusters and assignment of likelihood of malignancy using a predefined classifier.

Claim 7

A method of differentiating benign from malignant calcifications comprising the steps of: implementing an automatic detection and segmentation system with a pattern recognition process of breast calcifications from mammographic images of a patient; analyzing the shape and distribution of the calcifications and estimation of preselected parameters using image and non-image data from the patient's file; inputting the patient's age as a demographic feature that links images to patients; and differentiating between benign and malignant calcification clusters and assignment of likelihood of malignancy using a classifier, wherein the automated method yields detection and likelihood of malignancy.

¹ First Office Action page 2, lines 12-16

² First Office Action page 2, lines 19-23

³ MPEP §2143

⁴ MPEP §2412

I. Roberts teaches away from the instant invention

Roberts cannot be used as prior art for §103 obviousness as it teaches away from the claimed invention. If the proposed modification or combination of the prior art would change the principle of operation of the prior art being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious.⁵ If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification.⁶

Roberts teaches that an integral part of the instant invention- the ANN- is inadequate for classification. "Although they perform well, ANN's (Artificial Neural Networks) do not provide for meaningful explanation generation" (line 45 p1). In contrast, the instant invention teaches the use of an ANN. "Classification is done with a three-layer, feed forward artificial neural network (ANN) consisting of an input layer, one hidden layer and an output layer. The NevProp 1 backpropagation software is presently used" (para 67 p13). Kallergi explicitly teaches the use of an ANN. The ANN is explained at length (para 67-69 p13-14).

Roberts teaches the use of a Bayesian network over an ANN. "The ability of Bayesian networks to explain their reasoning is an important advantage over ANN's. Physicians generally will not accept and act on a computer system's advice without knowing the basis for the system's decision" (Roberts line 59.p1). Clearly, Roberts is discouraging the use of an ANN by unfavorably comparing an ANN to a Bayesian network. Robert's teaching is clear: ANN is not to be used with the Roberts invention.

An inventor reading the Roberts reference who still wished to use an ANN would not only avoid reliance on Roberts, but also conscientiously ignore it. There is neither an implicit

⁵ *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959).

⁶ *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)

nor explicit teaching of the use of an ANN in Roberts. Rather, Roberts suggests that the use on an ANN would render the instant invention inferior. Roberts cannot be used as prior art for §103 obviousness as it teaches away from the claimed invention.

II. There is not evidence of a reasonable expectation of success of the proposed combination.

The prior art can be modified or combined to reject claims as prima facie obvious as long as there is a reasonable expectation of success.⁷ Evidence showing that there was no reasonable expectation of success may support a conclusion of nonobviousness.⁸ In the instant invention, there is no reasonable expectation of success in combining Roberts with Bamberger because the visual amplification of possible calcifications taught by Bamberger would distort the results produced by the Roberts algorithm. The Roberts invention teaches the use of a series of calculations (p.9-11) that depend on an initial probability value assignment (p7 lines 15-40). Since neither Bamberger nor Roberts address the calibrations that must be made in the Roberts algorithm to accommodate the images enhanced via the Bamberger invention, there is not a reasonable expectation of success.

III. The combination does not teach all limitations

To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.⁹ Neither Roberts nor Bamberger teach automatic detection, an explicit limit of Claim 7. Since Bamberger teaches image enhancement rather than diagnosis, Bamberger teaches away from automatic detection and likelihood of malignancy in that Bamberger explicitly relies on the evaluation of a radiologist. "The system is designed to support radiologists' analyses by characterizing equivocal and suspicious findings detected on

⁷ *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

⁸ *In re Reinhart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976).

routine mammograms, so as to improve visualization of the suspected finding and to quantify the mammographic features of suspected lesions." (Bamberger line 20 p2). Since there is no recitation of automatic detection and likelihood of malignancy in either Roberts or Bamberger, the proposed combination fails to teach all of the limitations of the instant invention.

Conclusion

Entry of a Notice of Allowance is solicited. If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (813) 925-8505 is requested.

Very respectfully,

SMITH & HOPEN

Dated: September 6, 2007

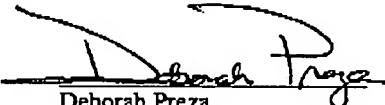
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CERTIFICATE OF FACSIMILE TRANSMISSION (37 C.F.R. 1.8(a))

I HEREBY CERTIFY that this response is being transmitted by facsimile to the United States Patent and Trademark Office, Art Unit 2624, Attn.: Jonathan C. Schaffer, (571) 273-8300 on September 6, 2007.

Dated: September 6, 2007


Deborah Preza

⁹ *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974).